

K240155 Cochlear Osia SystemApr 18, 2024
90 days to decisionK240155 · Product code: **PFO** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k240155/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Active Implantable Bone Conduction Hearing System (PFO)
Date received	Jan 19, 2024
Decision date	Apr 18, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cochlear Americas
Location	Englewood, CO, US
Contact	Whitney Alexander
510(k) history	20 submissions · 20 cleared · 2008-2024

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